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(54) Improved capsule construction

(57) Hard shell capsules have cylindrical, telescopically joinable coaxial cap and body parts each having a side wall, an open end and a closed end, the cap and the body being adapted to be mutually joined, the cap part having on its inner surface wall an annular ridge or an arrangement which functions as an annular ridge and spaced from said ridge or said arrangement towards the open end of the cap part means to hold cap and body in an exactly coaxial position.

These capsules show reduced loss, improved security of filling and provide a better printing quality at increased handling speed.

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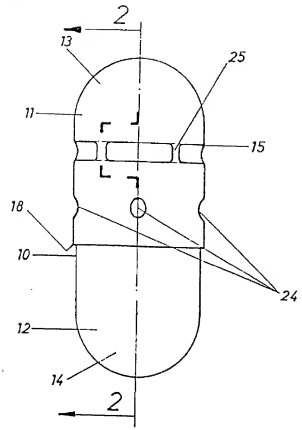

Fig. 1a

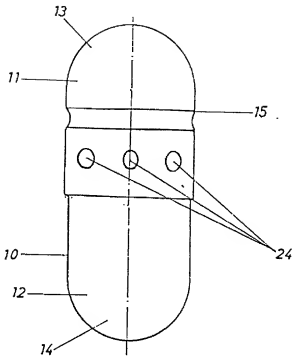

Fig. 1b

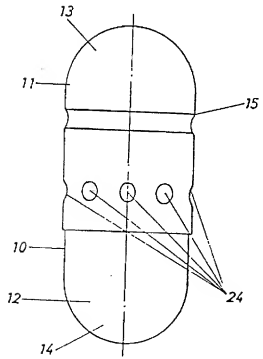

Fig. 1c

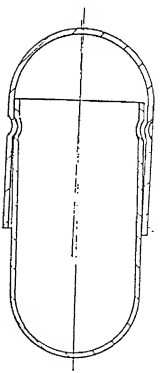

Fig. A

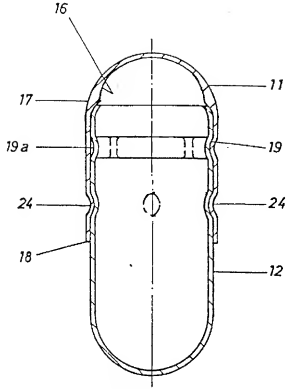

Fig. 2

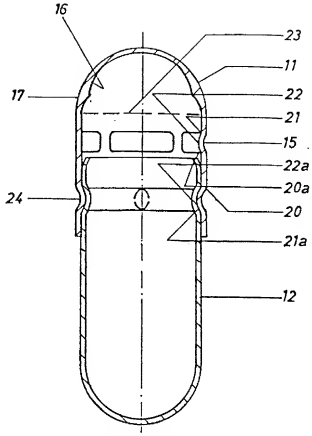

Fig. 3

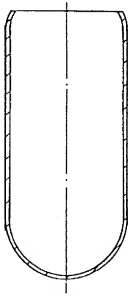

Fig. 4

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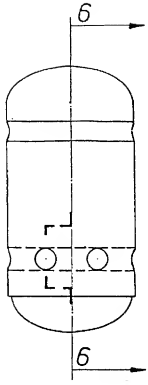

Fig. 5

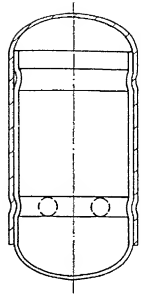

Fig. 6

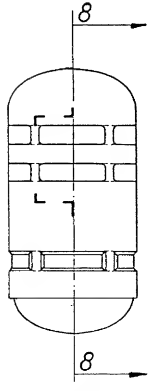

Fig. 7

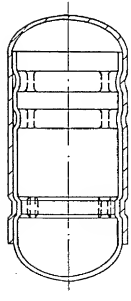

Fig. 8

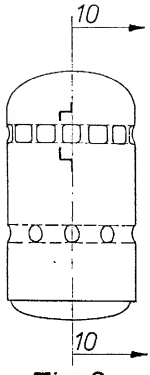

Fig. 9

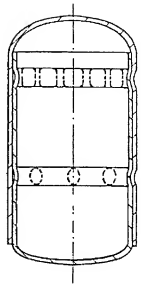

Fig. 10

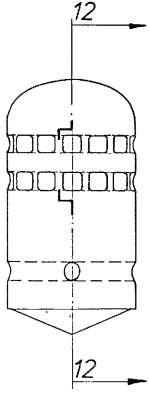

Fig. 11

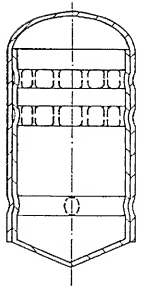

Fig. 12

SPECIFICATION

Improved capsule shape

The present invention relates to improved capsule shapes especially improved hard shell capsules having cylindrical, telescopically joinable, coaxial cap and body parts to provide a container for substances, e.g. for pharmaceuticals.

In the US-patent No. 3508678 a hard shell gelatin capsule is described being locked by a matching contact of a circumferential body groove with ridge means extending inward from the inner cap wall. Said capsule also having two separate indent means providing a pre-lock position.

These capsules have proved to be of a very good quality. However, in view of the increasing speed of the high speed filling controlling and printing machines, capsules are exposed to a rough handling and opening of even completely closed capsules may occur. It is the object of this invention to reduce the loss of capsules, improve the security of filling and provide a better printing quality at increased handling speed.

It appeared logical, that increasing the force resp. the friction to hold cap and body together, e.g. by increasing the height of the two protrusions being present, would produce the required result. However, it was found that this rather weakened the quality of the capsules.

It was surprisingly found that the capsules fulfill these requirements if their caps have an annular ridge or an arragement preferably of ridges which functions as an annular ridge and spaced from said ridge towards the open end of the cap parts there are means to hold cap and body in an exactly coaxial position. This means that the two rings that appear in the horizontal cross-section of the overlapping section of the cap and the body have at any height a same and common central point whereby deviation from the round form/or ovalisation is reduced to a minimum. It is a surprising perception that known capsules do not fulfill this condition but leave open a free movement between cap and body parts even they are coaxially joined, thus preventing an exactly coaxial position. This is shown in Figure A.

The present invention relates in particular to hard shell capsules having cylindrical, telescopically joinable coaxial cap and body parts each having a side wall, an open end and a closed end, the cap and the bdy being adapted to be mutually joined, characterized in that the cap part has on its inner surface wall an annular ridge or an arrangement which functions as an annular ridge being preferably an arrangement of ridge segments and/or protrusions and spaced from said ridge or said arrangement towards the open end of the cap part there is arranged means at a spacing being sufficient to hold cap and body in an exactly coaxial position.

The closed ends of the cap and body parts may be hemispherical, conical, pyramidical, flat or may have any other form. Preferably they are hemispherical, espcially for dip-molded capsules.

The annular ridge of the cap part is preferably circumferential and may be interrupted. The arrangement which functions as a ridge may e.g. be a number of protrusions or ridge segments which are arranged circumferentially. Such annular ridges or arrangements are known. If the cap is long enough there may be an additional annular ridge or arrangement which functions as an annular ridge.

The cross-section of the ridge can be a ring form or may have the form of a triangle or a polygon. The form, however, is not critical and depends on the manufacturing process of the cap part.

The means to hold the cap and body in an exactly coaxial position should not follow directly the annular ridge described above but should be at a spacing long enough so as to properly exhibit its function. This means can be an annular ridge, an arrangement of ridges and/or protrusions so as to hold cap and body in an exactly coaxial position.

The optimum arrangement has shown to be a number of protrusions arranged in an annular ring form, preferably in a symmetrical form, preferably adjacent protrusions having all the same distance from each other. The minimum number necessary are three protrusions, as two protrusions still allow enough movement of cap and body parts away from the coaxial position.

The depth of the protrusions is so dimensioned that the open end of the cap part and the open end of the body part can be easily joined together; the protrusions contacting the outer side wall of the body part and generating a slight pressure at the point of contact. There are arranged preferably 4, 5, 6, 7, 8, 9 or 10 protrusions, more preferably 6, 7, 8, 9 or 10 and most preferably 6 or 8. They may have different forms as to the cross-section, diameter, depth etc. Such forms of protrusions are known. Preferably they have all the same form and especially the same depth. It is also possible to use an annular ridge which is optionally interrupted.

As mentioned the distance between the annular ridge, which is situated preferably at the upper part of the cap near its closed end and the means to hold cap and body in an exactly coaxial position is important. The means to hold cap and body in the coaxial position should not follow directly the ridge near the end of the cap. Of course the actual length of this distance depends on the size of the capsule resp. the cap.

The annular ridge or the arrangement which functions as a ridge is located preferably at the upper part of the cap near its closed end, more preferably within the upper 50% of the cap length, calculated to the total length of the cap and most preferably within the upper 33% - 45% of the cap length near the closed end, calculated to the total length of the cap.

The means to hold cap and body in an exactly coaxial position is located preferably within 50% to 95% of the cap length, calculated from the top of the cap, towards its open end, more preferably within 50% to 85% of the total cap length calculated from the top of the closed end of the cap towards its open end, more preferably within 55 -

80% and most preferably within 65-75% of the total cap length calculated from the top of the closed end of the cap towards its open end. For two protrusions, these are preferably in the mentioned range of 65 - 75%.

The distance between the upper ridge and the means to hold cap and body in an exactly coaxial position is preferably not less than 2 mm more preferably not less than 2,5 mm. These measures are independent of the capsule size and especially suitable for the known capsule sizes 000, 00, 0, 1, 2, 3, 4, 5. For larger lengths of the cap the mentioned distances between ridge and the means may be also longer, preferably 3-5 mm, and for long caps also more than 5 mm depending on the length of the cap.

It is also possible to have more than one such means to hold cap and body in an exactly coaxial position especially if the cap is long enough, for example if the cap encloses the greater part of the cylindrical body side wall or its whole length. Two ridges and/or two means may follow each other and are preferably situated within the limits given above.

The body part may be smooth, i.e. without ridges or grooves. Preferably the body part has on its outer surface annular grooves or an arrangement of grooves matching with the ridge means of the inner surface of the cap so as to provide a substantially distortion-free, full lock between the cap and the body.

If the capsule is pre-locked the protrusions match preferably with the groove means of the body part. The dimensions can easily be chosen by a person skilled in the art.

The annular ridges and grooves are preferably interrupted in such a way that the spaces between the ridge segments act as vents to permit air to escape from within the capsule when joined.

The annular ridge of the cap may be represented by a constriction of the diameter of the cap or may have two slopes with an optional flat surface in between. The angles of the slopes or of the constriction are not critical and limited only by the limitation given by the manufacturing process. It means for instance that angles which cause an entrapment of air in the commonly used dipping process are to be avoided, which is known to the man skilled in the art.

The same is to be said for the dimensions of the protrusions. Different types of protrusions have become known and they are all suitable. Their basis can be e.g. oval, round or rectangular. The cross-section may have a round form or the form of a triangle or a polygon, e.g. two slopes and an optional flat surface in between. The angles of the slopes are not critical and only limited by the limitations given by the manufacturing process.

A further embodiment of the present invention is that the body has a reduced diameter of the outer wall in the area of its open end compared to the diameter of the rest of the outer wall. This reduces the danger of an abutment of the free edges of the capsule body and the capsule cap when they are telescoped. The dimension of the constriction is not critical. Preferably the axial width of the recess is about 10 to 20 times as large as its depth if the capsule body is produced by the dip-molding process. Preferably the constriction of the body matches with the closed end of the cap or a constriction of the cap to give a tight mechanical seal when the capsule is closed.

A further embodiment of the invention is characterized in that the closed end of the bdy has a hemispheroidal, conical, pyramidal or flat outside surface and that the cylindrical body side wall is totally enclosed within the inner cap side wall when the capsule is joined. Preferably the cylindrical outer side wall of the body covers practically completely the inner cylindrical side wall of the cap. This impedes separation of the joined capsules and renders them tamper-proof.

Capsules according to the present invention can be prepared by the dip molding process from gelatin in a manner known per se. It is also possible to prepare them from hydrophilic materials like gelatin or starch derivatives or mixtures thereof or from native starch by injection molding as described in the European Patent Applications Nos. 83 301 642,1 and 89 300 940.8. Capsules according to the present invention are preferably made from gelatin by the dip molding process or from gelatin or starch by injection molding.

In addtion to the advantages of the capsules of the present invention as mentioned above, capsules according to the invention when produced from gelatin or gelatin containing materials give also excellent results if sealed with a liquid sealing process. Such liquid sealing rpocess employs an agent preferably containing 5 - 95 % of water and 95 - 5 % of alcohol, which preferably is ethanol as described e.g. in the USP 3 073 087 or the European Patent Application 83 305 330.9. Sealing can be carried out at room temperature, but preferably at a temperature of 40 - 80°C with heated air, with infra-red or other heating means, preferably with heated air or infra-red, during a short period of time e.g. 1-5 minutes. According to the sealing conditions applied capsules are obtained which are tamperproof or liquid-proof. Using a temperature of 40 - 60°C and an alcohol-water ratio of approx. 40 : 60 till 95 : 5 give excellent liquid proofness. The alcohol is preferably ethanol. Preferably an ethanol/water mixture of 75 - 95% ethanol and a temperature of 40 - 60°C is used. The invention refers also to such a sealing process using these conditions as well as to capsules sealed by such method.

A further embodiment of the present invention is that the wall of the cap and/or the body of these capsules represent a foam, such as it is obtained by dip molding, the film-forming mixture obtained e.g. by a microdispersion of a gas, such as air, in a gelatin solution. Such capsules have distinct advantages as described in the European patent application No.83 304 741.8 (Publication Nr. 110 502).

Figure 1a, 1b and *1c* show a side elevation view of preferred capsule shapes.

Figure 2 is a side-sectional view (along the 2-2-axis of Figure 1a) of the locking section of a pre-

ferred embodiment in completely locked form.

Figure 3 corresponds to a capsule according to Figure 2, but in pre-locked form.

Figure 4 is a side-sectional view of the principle of a body part with a diameter restriction at the open end.

Figure 5 shows a side elevation view of an embodiment of the present invention wherein the cap covers completely the cylindrical wall of the body, the body having a spherical end.

Figure 6 is a side-sectional view of Figure 5.

Figure 7 shows a side elevation view of an embodiment of the present invention differing from Figure 5 resp. Figure 6 by having two annular ring systems.

Figure 8 is a side-sectional view of Figure 7.

Figure 9 shows a side elevation of a further embodiment, analogous to Figure 5, having air vents, 6 protrusions and a "flat" end of the body.

Figure 10 shows a side-sectional view of Figure 9.

Figure 11 shows a side elevation view of a further embodiment of the present invention.

Figure 12 shows the side-sectional view of Figure 11.

The capsules 10 shown in Figure 1a), 1b) and 1c) have a cap part 11 and a body part 12, both being closed at the ends 13 resp. 14. The cap 11 has a circumferential ridge 15, which may be interrupted by air vents. The cap has an open end and between this open end and the ridge 15, there are four (Figure 1a), six (Figure 1b) or eight (Figure 1c) protrusions 24. The protrusions 24 need not necessarily all have the same form. The details of the cap 11 with the outer wall 17 and the inner wall 16 are shown in Figure 2 and Figure 3. The inner wall 16 of the cap shows a ridge 19 corresponding to the restriction 15 shown on the outer wall. The ridge 19 has an angular cross-section, shown on the inner wall with the bevels 20 and 21 meeting at the apex 22.

The closed end 13 is preferably rounded or hemispherical but the shape is not critical. If desired, the cap end can have other shapes. The inner cap wall 16 proceeding from the open end 18 to the line 23, which is the shoulder line, has a slight narrowing diametral taper of the order of 0.01 cm per cm exclusive of ridge 19 and indent means 24.

In Figure 2 the cap and body parts are shown in the fully locked position whereas in Figures 3 the cap and body parts are shown in partly closed or pre-locked position with the open end of the body advanced towards the leading bevel 20 of the ridge 19. The body has a groove 19a which matches the ridge 19. Groove 19a has a leading bevel 20a and a trailing bevel 21a which join at apex 22a. In Figure 2, as indicated, the cap and body have been pressed together from the partly closed pre-locked or semi-locked position into the fully closed, locked position. Here the constriction at the end of the body matches with the cap to give a tight mechanical seal. In the locked position ridge 19 and body groove 19a are in a matching fit or mechanical fit as distinguished from a friction fit, with their respective bevels and apexes in close conformity. In this position the open body end has advanced into the cap to a point near or preferably just beyond the shoulder line 23. The body like the cap is tapered in the same degree and in the direction from its open end to its closed end. The body taper and the body dimensions in relation to the taper and dimensions of the cap also are such as to provide a relatively distortion-free fit in the pre-locked position shown in Figure 3; the fit between adjacent wall surfaces of the cap and body advantageously permits the passage of air. The pre-locked fit in the area of the indent 24 is preferably a mechanical fit as distinguished from a friction fit so that it is substantially distortion-free.

This construction provides for increased passage means or air vent means 25 so as to permit the escape of compressed air contained within the capsule occasioned, for example, by the sudden joining of the body and cap parts into locked position. Thus, the release of air advantageously avoids any tendency of the cap and body to reopen after filling.

Capsules according to the present invention can be used as containers resp. for the exact dosage for food stuffs pharmaceuticals, chemicals, dyestuffs, spices, fertilizing combinations, seeds, cosmetics and agricultural products and matrices of various shapes and sizes for food-stuffs, pharmaceuticals, chemicals, dyestuffs, spices, fertilizing combinations, seeds, cosmetics and agricultural products in any useful form such as powder or liquids. Special forms such as microdispersions within the matrix and released from it through disintegration and/or dissolution and/or bioerrosion and/or diffusion resulting in a controlled release delivery system for the enclosed substance, and medical and surgery products, formed from the compositions or the foams thereof can also be filled into capsules of the present invention.

CLAIMS

1. Hard shell capsules having cylindrical, telescopically joinable coaxial cap and body parts each having a side wall, an open end and a closed end, the cap and the body being adapted to be mutually joined, characterized in that the cap part has on its inner surface wall an annular ridge or an arrangement which functions as an annular ridge being preferably an arrangement of ridge segments and/or protrusions and spaced from said ridge or said arrangement towards the open end of the cap part there is arranged means at a spacing being sufficient to hold cap and body in an exactly coaxial position.

2. Hard shell capsules according to claim 1, wherein the annular ridge is a circumferential ridge which optionally is interrupted.

3. Hard shell capsules according to claim 1, wherein the annular ridge is an arrangement of circumferentially arranged ridges or protrusions.

4. Hard shell capsules according to any of the claims 1-3, having an additional annular ridge or an additional arrangement of ridges and/or protrusions.

5. Hard shell capsules according to any of the claims 1-4, wherein the ridge(s) is(are) located at the upper part of the cap near its closed end within the upper 50% of the cap length calculated to the total length of the cap.

6. Hard shell capsule according to any of the claims 1-5, wherein the means to hold cap and body in an exactly coaxial position is represented by a minimum of three protrusions, preferably in a symmetrical arrangement. preferably adjacent protrusions having all the same distance from each other.

7. Hard shell capsule according to claim 6, wherein as said means are arranged 4, 5, 6, 7, 8, 9 or 10 protrusions, preferably 6, 7, 8, 9 or 10, preferably 6 or 8 protrusions, preferably in a symmetrical arrangement, preferably all protrusions having the same form, preferably adjacent protrusions having all the same distance from each other.

8. Hard shell capsule according to any one of claims 1-5, wherein said means is an annular ridge which is optionally interrupted.

9. Hard shell capsule according to any one of the claims 1-8, wherein there are two means to hold cap and body in an exactly coaxial position.

10. Hard shell capsules according to any one of the claims 1-9, wherein the means to hold cap and body in an exactly coaxial position is located within 50 - 95% preferably within 50-85%, preferably within 55-80% and preferably within 65-75% of the total cap length, calculated from the top of the closed end of the cap towards its open end.

11. Hard shell capsules according to any one of the claims 1-10, wherein the body part has a smooth outside surface.

12. Hard shell capsule according to any one of the claims 1-11, wherein the body part has on its outer surface annular grooves or an arrangement of grooves matching with the ridge means of the inner surface of the cap so as to provide a substantially distortion-free, full lock between the cap and the body.

13. Hard shell capsules according to any one of the claims 1-12, wherein the annular ridges and grooves are interrupted in such a way that the spaces between the ridge segments act as vents to permit air to escape from within the capsule when joined.

14. Hard shell capsule according to any one of the claims 1-13, wherein the annular ridge of the cap is a constriction of the diameter of the cap.

15. Hard shell capsule according to any one of the claims 1-14, wherein the annular ridge has two slopes and an optional flat surface in between.

16. Hard shell capsule according to any one of the claims 1-15, wherein the protrusions have an oval, round or rectangular basis and in the cross-section show two slopes and an optional flat surface in between.

17. Hard shell capsule according to any one of the claims 1-16, wherein the body has a reduced diameter of the outer wall in the area of its open end compared to the diameter of the rest of the outer wall.

18. Hard shell capsule according to claim 17, wherein the constriction of the body matches with the closed end of the cap or a constriction of the cap to give a tight mechanical seal when the capsule is closed.

19. Hard shell capsule according to any one of the claims 1-18, wherein the cylindrical body side wall is totally enclosed within the inner cap side wall when the capsule is joined.

20. Hard shell capsule according to any one of the claims 1-19, made by the dip molding process from gelatin.

21. Hard shell capsule according to any one of the claims 1-19, made from gelatin or starch derivatives or mixtures thereof or from native starch by injection molding.

22. Hard shell capsule according to any one of the claims 1-20, wherein the wall of the cap and/or the body part represent a foam.

23. Hard shell capsule made from gelatin or gelatin containing materials, according to any one of the claims 1 - 22, being sealed by a liquid sealing process.

24. Hard shell capsules according to claim 23 being sealed by a sealing liquid containing 5 - 95% of water and 95 - 5% alcohol, preferably ethanol at a temperature of up to 80°C, preferably at a temperature of 40 - 60°C during a short period of time.

25. Hard gelatin capsules according to claim 24 being sealed with an alcohol-water mixture with an alcohol: water ratio of 40-60 to 95:5 at a temperature of 40 - 60°C, during 1 - 5 minutes.

26. Hard shell capsule according to any one of the claims 1-25, to be used for the exact dosage for food stuffs pharmaceuticals, chemicals, dyestuffs, spices, fertilizing combinations, seeds, cosmetics and agricultural products and matrices of various shapes and sizes for food-stuffs, pharmaceuticals, chemicals, dyestuffs, spices, fertilizing combinations, seeds, cosmetics and agricultural products in any useful form such as powder or liquids, special forms such as microdispersions within the matrix and released from it through disintegration and/or dissolution and/or bioerrosion and/or diffusion resulting in a controlled release delivery system for the enclosed substance, and medical and surgery products, formed from the compositions or the foams thereof.

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